

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

THE HONORABLE ANDREW J. GUILFORD, JUDGE PRESIDING

CERTIFIED TRANSCRIPT

ALLERGAN USA, INC., et al., }
Plaintiff, }
vs. } SACV-13-1436-AG
MEDICIS AESTHETICS, INC.,)
et al.,)
Defendants. }
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REPORTER'S TRANSCRIPT OF PROCEEDINGS

Santa Ana, California

August 12, 2014

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1 SANTA ANA, CALIFORNIA; TUESDAY, AUGUST 12, 2014; 9:04 A.M.

08:56 2 THE CLERK: SACV-13-1436-AG, Allergan USA, Inc.,
09:04 3 et al., versus Medicis Aesthetics, Inc., et al.

09:05 4 THE COURT: Good morning.

09:05 5 Let's have appearances, please.

09:05 6 MS. GARNER: Good morning, Your Honor. Laura
09:05 7 Garner, and I have with me Michael Kane and Elizabeth
09:05 8 Flanagan.

09:05 9 MR. NORRIS: Good morning, Your Honor. Donald
09:05 10 Norris for the defendants.

09:05 11 MR. CAVANAUGH: Good morning, Your Honor. Bill
09:05 12 Cavanaugh on behalf of the defendants.

09:05 13 MR. HOWARD: Good morning, Your Honor. Scott
09:05 14 Howard on behalf of the defendants.

09:05 15 THE COURT: All right, welcome all. I hope you
09:05 16 all received the tentative that was sent out.

09:05 17 I am prepared to describe how we should proceed,
09:05 18 but I am also open to suggestions. Do the parties before me
09:06 19 have any suggestions on how we should proceed?

09:06 20 MR. CAVANAUGH: Your Honor, we conferred briefly.
09:06 21 Based on the Court's tentative ruling, it certainly appears
09:06 22 that the Court understands the technology at issue in this
09:06 23 case, and we don't think -- I don't think either side
09:06 24 believes that a tutorial is really necessary.

09:06 25 THE COURT: I agree.

09:06 1 MR. CAVANAUGH: From our perspective at oral
09:06 2 argument, there is only really one claim construction issue
09:06 3 we would like to take up with the Court, and that's on the 2
09:06 4 to 20 percent degree of cross-linking issue.

09:06 5 THE COURT: I found that one of the most
09:06 6 interesting. So you want to talk about 2 to 20 percent.

09:06 7 MR. CAVANAUGH: Right.

09:06 8 MR. KANE: Your Honor, as counsel said, we did
09:06 9 discuss it the hallway, and we don't believe that a
09:06 10 tentative is necessary.

09:07 11 THE COURT: You mean a tutorial.

09:07 12 MR. KANE: We don't believe that a tutorial is
09:07 13 necessary. We have reviewed the tentative as well. We
09:07 14 stand by our constructions and proposals that were submitted
09:07 15 in the briefing, but in the sense of what we do today to
09:07 16 accomplish and move things forward, Allergan is prepared to
09:07 17 submit on the tentative and has no issues that it would like
09:07 18 to raise with the Court. Obviously we would like a chance
09:07 19 to respond to the defendants on the 2 to 20.

09:07 20 THE COURT: All right, let's hear 2 to 20. We
09:07 21 will go back and forth on that. That really helps focus,
09:07 22 and that's one of the reasons we issue tentatives.

09:07 23 MR. CAVANAUGH: Thank you, Your Honor.

09:07 24 THE COURT: By the way, it's always helpful to
09:07 25 focus on any specific passages or lines or sections in the

09:08 1 tentative, but proceed as you wish.

09:08 2 MR. CAVANAUGH: Your Honor, I think it would be
09:08 3 helpful if the Court has the '475 patent because I will
09:08 4 refer to sections there. No graphics are really necessary.

09:08 5 THE COURT: Very well. I agree. I'll get the
09:08 6 '475 patent. Go ahead.

09:08 7 MR. CAVANAUGH: Your Honor, in the tentative, you
09:08 8 concluded that this was not a clear statement of the scope
09:08 9 of the invention in column 9 at 30 to 34. The Court gave a
09:08 10 number of reasons for that conclusion while noting I believe
09:08 11 that it is a close question.

09:08 12 Let me start with column 9, Your Honor, and the
09:08 13 language -- and the two sentences that follow that
09:09 14 statement.

09:09 15 THE COURT: Just a moment. I have to gather the
09:09 16 patent.

09:09 17 MR. CAVANAUGH: I know it's Exhibit A to Ms.
09:09 18 Flanagan's deposition.

09:09 19 THE COURT: All right. I have it.

09:09 20 MR. CAVANAUGH: Column 9, Your Honor, line 30,
09:09 21 this is what we are contending is the clear statement of the
09:09 22 scope of the invention: "The degree of cross-linking in the
09:09 23 HA component of the present compositions is at least about
09:09 24 2 percent and is up to about 20 percent." The two sentences
09:09 25 that follow when read in context with that are simply

09:09 1 pointing out ranges that fall within 2 to 20.

09:09 2 Now, in its decision -- and, for example, it says:
09:09 3 "In some embodiments, the degree of cross-linking is less
09:10 4 than about 6 percent, for example, is less than about
09:10 5 5 percent. In other embodiments, the degree of
09:10 6 cross-linking is greater than 5 percent, for example, is
09:10 7 about 6 to 8 percent," and they talk about 4 to 12 percent.

09:10 8 Now, in its tentative, the Court noted, well,
09:10 9 there's not necessarily a lower bound being provided, and
09:10 10 the Court noted certain claims that refer to less than 6
09:10 11 percent and less than 5 percent. I have two points as to
09:10 12 that, Your Honor.

09:10 13 The first is those are dependent claims. You have
09:10 14 an independent claim that talks about the composition, which
09:10 15 we would say is defined by 2 to 20 percent degree of
09:10 16 cross-linking, so those are dependent claims.

09:10 17 The second point, and perhaps more importantly, is
09:10 18 if you look at column 16 and you look at those dependent
09:11 19 claims, claim 5 talks about less than about 6 percent.
09:11 20 Claim 6 talks about less than about 5 percent, but then
09:11 21 significantly, Your Honor, what the inventor does in
09:11 22 dependent claim 7 -- it talks about the soft tissue filler
09:11 23 of claim 4 wherein the HA composition has a degree of
09:11 24 cross-linking of about 2 percent. He departs from using the
09:11 25 phrase "less than" and specifically uses the phrase "of

09:11 1 about 2 percent" thereby following the language in the
09:11 2 specification, which we say defines the scope of the
09:11 3 invention, up to 20 and at least 2 percent.

09:12 4 THE COURT: If I were to say that range is not
09:12 5 consistently applied throughout the specifications and
09:12 6 claims, what would your response be?

09:12 7 MR. CAVANAUGH: I think it is applied
09:12 8 consistently, Your Honor, because the only references to
09:12 9 degree of cross-linking are always within 2 to 20 in all the
09:12 10 examples that are provided. When they use the term "present
09:12 11 composition," the inventor when talking about specific
09:12 12 embodiments is very clear. He says, for example, in some
09:12 13 embodiments -- in column 7 at lines 11, 20, 29, he uses the
09:12 14 phrase "in other embodiments," column 7, line 18.

09:12 15 The Court notes that in one instance the inventor
09:13 16 uses the phrase "present description," which is different
09:13 17 from "present composition," but in that context, it's
09:13 18 clearly a specific example -- and they're talking about
09:13 19 column 14 -- that illustrates the release pattern of
09:13 20 Lidocaine. So I think that there is a consistency
09:13 21 throughout the specification. They're talking about this
09:13 22 range, 2 to 20. That's what the inventor studied, and they
09:13 23 define the clear scope of that invention.

09:13 24 Now, in its opinion, the Court notes, well, that's
09:13 25 only used once. Two thoughts on that, Your Honor. The

09:13 1 first is if you look at the Astrazeneca case where they
09:13 2 found that Astrazeneca based on a statement in the invention
09:14 3 that the scope of the invention was simply the six
09:14 4 identified salts, there is one reference to that in the
09:14 5 specification. There is a vaguer description in the
09:14 6 abstract, but if you focus on the body of the specification,
09:14 7 in Astrazeneca, they just said it once.

09:14 8 If you think about it, this isn't the type of
09:14 9 statement that you would necessarily repeat throughout the
09:14 10 specification. You're saying here is my range. This is
09:14 11 what I have invented, 2 to 20 percent, and then they go on
09:14 12 to discuss the specific examples that follow.

09:14 13 The Court also notes an issue of claim
09:14 14 differentiation, that claim 27 --

09:15 15 THE COURT: Well, isn't it superfluous for claim 27
09:15 16 to be stating that if I were to adopt your definition, and
09:15 17 isn't that a pretty powerful rule of construction?

09:15 18 MR. CAVANAUGH: I would say no, Your Honor,
09:15 19 because if you look at the Astrazeneca case and the Edwards
09:15 20 case, in both of those Federal Circuit decisions, the
09:15 21 patentee raised claim differentiation. In Astrazeneca,
09:15 22 there was a statement in the specification: The present
09:15 23 invention is based on the following six salts. There is
09:15 24 then a claim that recites those six salts.

09:15 25 Astrazeneca argued claim differentiation. Our

09:15 1 invention isn't limited to those six salts because there is
09:15 2 a specific claim on it. The Federal Circuit disagreed and
09:15 3 said, no, claim differentiation can't be used to override a
09:15 4 clear statement of the scope of the invention.

09:16 5 THE COURT: Well, is this a clear statement of the
09:16 6 scope of the invention?

09:16 7 MR. CAVANAUGH: It says the present composition
09:16 8 and a range of 2 to 20 percent. I will give you a second
09:16 9 example of where claim differentiation while a rule of thumb
09:16 10 is not a rigid rule. In addition to the Astrazeneca case,
09:16 11 the Edwards case, involving grafts that are intraluminally
09:16 12 introduced into the body. The specification speaks of
09:16 13 the term -- the claim spoke of the term "graft." The
09:16 14 District Court claim construction said "graft" is defined as
09:16 15 "intraluminal grafts." Even though the claim only says
09:16 16 "graft," they added the term "intraluminal" based on the
09:17 17 language of the specification.

09:17 18 Edwards argued we have a claim that says "inside
09:17 19 of a vessel," and that's the definition of "intraluminal."
09:17 20 Claim differentiation. Our claim should not be limited to
09:17 21 intraluminal grafts because we have a claim that essentially
09:17 22 says "intraluminal." Again, as in the Astrazeneca case, the
09:17 23 Court disagreed and found claim differentiation could not be
09:17 24 used in that instance to override a clear statement of the
09:17 25 scope of the invention in the patent because the patentee

09:17 1 had referred throughout the specification to grafts as
09:17 2 intraluminal.

09:17 3 So I don't think claim differentiation ends up
09:18 4 being a powerful argument for the patentee in this instance,
09:18 5 Your Honor, based on Astrazeneca and based on the Edwards
09:18 6 decision. Here there is a clear unequivocal statement.
09:18 7 Here is the range of the present compositions of my
09:18 8 invention.

09:18 9 Finally, Your Honor, the Court noted that, well,
09:18 10 this wasn't used to distinguish prior art, but that's not
09:18 11 the sole test for whether there has been a clear statement
09:18 12 of the scope of the invention.

09:18 13 THE COURT: Surely you don't think I am saying
09:18 14 that's the sole test.

09:18 15 MR. CAVANAUGH: No, I didn't, Your Honor.

09:18 16 THE COURT: You mean it's a factor.

09:18 17 MR. CAVANAUGH: But the Federal Circuit -- for
09:18 18 example, in the Edwards case, during the prosecution they
09:18 19 deleted the term "intraluminal." Edwards said how could
09:19 20 this be construed as limited to "intraluminal" when we
09:19 21 deleted that term at one point during the prosecution
09:19 22 history? The Federal Circuit said it wasn't material. Your
09:19 23 deletion of it during prosecution wasn't particularly
09:19 24 material, so you can't cite it.

09:19 25 Here, Your Honor, the fact that -- what didn't

09:19 1 come up during the prosecution history doesn't answer the
09:19 2 question whether the inventor limited it for purposes of --
09:19 3 because if you look at all the prior art they cite, whether
09:19 4 it was done for those purposes or whether because as the
09:19 5 specification makes clear that's what they were testing.
09:19 6 That was the range that they were testing.

09:19 7 So for all those reasons, Your Honor, we think
09:19 8 this does come down to a clear statement. I think the
09:19 9 language of those dependent claims strengthens that
09:19 10 argument because if the inventor's view was I'm not bound
09:20 11 by this 2 percent, why would that dependent claim be
09:20 12 written differently than the two others? In that
09:20 13 dependent claim, he confirmed not that 2 percent -- that's
09:20 14 his lower boundary -- but that confirms what's in the
09:20 15 specification.

09:20 16 THE COURT: Is it your position that the range 2
09:20 17 to 20 is consistently applied throughout the specifications
09:20 18 and claims?

09:20 19 MR. CAVANAUGH: I believe it is, Your Honor.

09:20 20 THE COURT: Okay. Let's hear from the plaintiff,
09:20 21 and that might be a good lead-off question to the plaintiff.

09:20 22 MR. KANE: Your Honor, we do not believe that it's
09:20 23 used consistently throughout the specification or the
09:20 24 claims. I think what is important is how often it is used,
09:21 25 when it is used, and where it is used. I think you have to

09:21 1 look at the entire invention here.

09:21 2 I will refer the Court to the '475 Patent as well.

09:21 3 I would start with the title of the patent, "Hyaluronic
09:21 4 Acid-Based Gels Including Lidocaine." So that's the title.
09:21 5 That's telling what the invention is about, adding
09:21 6 lidocaine.

09:21 7 If you look at the abstract --

09:21 8 THE COURT: You know what I am going to ask you to
09:21 9 do? Put it on the elmo.

09:21 10 MR. KANE: Your Honor, if you look at the
09:22 11 abstract, the very first sentence says: "Disclosed herein
09:22 12 are soft tissue fillers, for example, dermal and subdermal
09:22 13 fillers based on hyaluronic acids and pharmaceutically
09:22 14 acceptable salts thereof. In one aspect, the hyaluronic
09:22 15 acid-based compositions include a therapeutically effective
09:22 16 amount of at least one anesthetic agent, for example,
09:22 17 lidocaine." There's nothing here about the degree of
09:22 18 cross-linking. There is nothing here about that. It's all
09:22 19 about the gel with the anesthetic agent.

09:22 20 We then continue through the patent. I'm
09:23 21 referring to the Background Section, Your Honor. This is at
09:23 22 column 2 starting at about line 29. They identify the
09:23 23 problem that the patent is attempting to solve. "It has
09:23 24 been proposed to incorporate certain therapeutic agents, for
09:23 25 example, anesthetic agents such as Lidocaine." Then it

09:23 1 continues in the last paragraph of the background: "It is
09:23 2 an objective of the HA-based soft filler compositions and
09:23 3 methods of making them" --

09:23 4 THE COURT: "Making and using them."

09:23 5 MR. KANE: Yes. "Making and using them as
09:23 6 described herein to provide soft tissue fillers that do not
09:24 7 cause allergic reactions in patients, are biocompatible and
09:24 8 stable and usable in vivo and include one or more local
09:24 9 anesthetic agents." Again, there is no description about
09:24 10 the degree of cross-linking or any kind of range of degree
09:24 11 of cross-linking.

09:24 12 Then you move to the summary of the invention, the
09:24 13 very first description of what the invention is. Again,
09:24 14 Your Honor, the present description relates to soft tissue
09:24 15 fillers, for example, dermal and subdermal fillers based on
09:24 16 hyaluronic acid, and pharmaceutically acceptable salts of
09:24 17 HA" -- and they give some examples -- "including a
09:24 18 therapeutically effective amount of at least one anesthetic
09:24 19 agent."

09:24 20 Then it continues. Again, Your Honor, in terms of
09:25 21 is it consistent, this sentence is very important starting
09:25 22 at line 42: "The present HA compositions describing the
09:25 23 invention, including at least one anesthetic agent, have
09:25 24 enhanced stability relative to conventional HA-based
09:25 25 compositions, for example, Lidocaine," and it continues.

09:25 1 There is a description of the invention, the present HA
09:25 2 compositions. There is no discussion about the degree of
09:25 3 cross-linking.

09:25 4 The entire invention here, the disclosure, the
09:25 5 problem that is being solved is this is going to tell the
09:25 6 world how to make -- and it's the first of its kind of HA
09:25 7 fillers -- that it can have Lidocaine that is stable and
09:25 8 usable. That's the problem. It has nothing to do with the
09:25 9 degree of cross-linking.

09:26 10 THE COURT: Hold on. I'm not getting that
09:26 11 statement. Cross-linking does affect stability doesn't it?

09:26 12 MR. KANE: But the degree of cross-linking is not
09:26 13 the novel invention. That's not the novel aspect of this.
09:26 14 There were HA fillers that had a degree of cross-linking
09:26 15 between 2 and 20 before this invention. There's nothing
09:26 16 here where the applicant is saying other people have a
09:26 17 degree of cross-linking at 50. Other people have a degree
09:26 18 of cross-linking at 1. I have found out that the important
09:26 19 range is 2 to 20. That's my invention.

09:26 20 It's not what this is about at all. It's all
09:26 21 about being able to take an HA filler that has the desirable
09:26 22 characteristics for the treatment and being able to add
09:26 23 Lidocaine and maintain a useable stable product.

09:27 24 If you continue on in the summary --

09:27 25 THE COURT: Hold on just one moment.

09:27 1 MR. KANE: Certainly.

09:27 2 THE COURT: Why is there a mention of 2 to 20?

09:27 3 MR. KANE: Well, that is a range that was looked
09:27 4 at, but that's not limiting, Your Honor.

09:27 5 THE COURT: When I asked a specific question about
09:27 6 whether that range is consistently applied, you said no,
09:27 7 correct?

09:27 8 MR. KANE: Correct.

09:27 9 THE COURT: But are all your inconsistent
09:27 10 applications within that range?

09:27 11 MR. KANE: We don't think so, no. As I will show
09:27 12 you, in the summary of the invention, there are
09:27 13 inconsistencies. Again, at the very beginning of the
09:28 14 patent --

09:28 15 THE COURT: Inconsistencies outside that range?

09:28 16 MR. CAVANAUGH: Yes. There are statements here,
09:28 17 for instance, less than 5 percent at the very beginning of
09:28 18 the patent.

09:28 19 THE COURT: Five percent is within the range of 2
09:28 20 to 20.

09:28 21 MR. KANE: One percent is less than five percent
09:28 22 and is not within the range.

09:28 23 THE COURT: I understand your point.

09:28 24 MR. KANE: If you look at the summary of the
09:28 25 invention -- we are at column 3, line 25. It says, "the

09:28 1 degree of cross-linking less than about 5 percent. Then it
09:28 2 it continues, "for example, about 2 percent." It doesn't
09:28 3 say greater than 2 percent. It doesn't say less than 5 and
09:28 4 greater than 2. It says less than 5, for example, about 2.

09:28 5 THE COURT: Well, "about" is the phrase the
09:28 6 defendants are proposing.

09:28 7 MR. KANE: I understand. I will come to that in a
09:28 8 minute, but certainly it doesn't say greater than 2 or
09:29 9 greater than about 2.

09:29 10 If we continue down to column -- again, we are
09:29 11 still in column 3, lines 63 to 64. "The HA component has a
09:29 12 degree of cross-linking of less than about 6 percent or less
09:29 13 than about 5 percent." No mention of 2. It covers 1. It
09:29 14 covers one-half. It covers three-quarters. Unequivocal.

09:29 15 Column 4 --

09:29 16 THE COURT: Unequivocal? You can't say that less
09:29 17 than 5 percent unequivocally references 1 percent.

09:29 18 MR. KANE: I think it covers 1 percent.
09:29 19 Unequivocally -- there is no limiting language about that.

09:29 20 THE COURT: Okay.

09:29 21 MR. KANE: Same thing in column 4. Again, still
09:29 22 in the summary of the invention. "HA component having a
09:29 23 degree of cross-linking of less than 5 percent."

09:30 24 THE COURT: When you're reading from it, I just
09:30 25 want the record to be clear that it says, "less than about 5

09:30 1 percent."

09:30 2 MR. KANE: I apologize.

09:30 3 Then at line 17, it says: "HA composition with a
09:30 4 degree of cross-linking less than about 5 percent." So in
09:30 5 the Background Section, there is no discussion about the
09:30 6 degree of cross-linking at all. It's all about adding
09:30 7 Lidocaine. In the beginning of the summary of the
09:30 8 invention, the discussion is about HA fillers with
09:30 9 Lidocaine. There is no limitation at all on the amount of
09:30 10 degree of cross-linking. Then here throughout the summary
09:30 11 of the invention, there are four references to a degree of
09:30 12 cross-linking, none of which have the 2 to 20 range, one of
09:30 13 which says about 2, but three of which has no mention of 2
09:30 14 at all.

09:30 15 This is absolutely inconsistent with -- that the
09:31 16 invention is limited and consistently limited to 2 to
09:31 17 20 percent. As the Court knows, the case law is very clear.
09:31 18 The Phillips case is very clear. The Thorner case, which is
09:31 19 a relatively recent Federal Circuit case, is again very
09:31 20 clear. There are only two exceptions to this general rule
09:31 21 that you get the plain meaning, lexicography -- they are not
09:31 22 arguing lexicography here -- or a clear disavow of scope,
09:31 23 meaning words of "manifest exclusion."

09:31 24 THE COURT: What are you reading from?

09:31 25 MR. KANE: I am reading from Thorner, "words of

09:31 1 manifest exclusion consistently and uniformly being used
09:32 2 throughout the specification. They just aren't here, and
09:32 3 the Court has noted that they're not here.

09:32 4 The other portions of the intrinsic evidence
09:32 5 conflict with that interpretation. As the Court noted in
09:32 6 its tentative order, this 2 to 20 percent doesn't ever
09:32 7 appear except in claim 27, but it's never anywhere else in
09:32 8 the specification. If that was important, if the invention
09:32 9 was so limited, you would have expected to see this
09:32 10 described elsewhere. You don't.

09:32 11 The Court also noted that -- again, claims 5, 6,
09:32 12 and 7 that we just went through are also inconsistent. In
09:32 13 fact, those claims come right out of the summary of the
09:32 14 invention that I just went through. There is no discussion
09:33 15 of 2 and 20 in the summary of the invention, so counsel's
09:33 16 argument that claims 5, 6 and 7 confirm that we are in the
09:33 17 range is actually completely inconsistent with the summary
09:33 18 of the invention.

09:33 19 Actually I would argue claim 7 doesn't confirm any
09:33 20 kind of a lower limit. If it was going to confirm some
09:33 21 lower limit, there would be language such that it would say
09:33 22 greater than about 2 percent, 2 percent or greater,
09:33 23 something like that. This is actually calling out it's
09:33 24 about 2 percent, which of course has to have some value
09:33 25 below 2 percent. It's not saying 3 percent. That claim

09:33 1 wouldn't cover 6 percent. It only covers about 2 percent.

09:33 2 So it's not calling out a range. It's calling out --

09:33 3 THE COURT: Patentable would be discovery of a 2
09:33 4 to 20 percent range -- the problem has been solved, and it's
09:34 5 2 to 20 percent. Do you think that would be patentable?

09:34 6 MR. KANE: I don't think so. I think the people
09:34 7 who were doing this -- I think Allergan's previous products
09:34 8 fell within that range. There's lots of products that fell
09:34 9 within that range that are all prior art, so that can't be
09:34 10 the novel aspect. That's not the invention here, finding a
09:34 11 new range.

09:34 12 THE COURT: My question does not preclude it from
09:34 13 being part of the novel aspect, but go ahead. I understand.

09:34 14 MR. KANE: That alone I don't think could be a
09:34 15 distinguishing feature because there was present plenty of
09:34 16 art out there that had cross-linking in that range.

09:34 17 As the Court noted, there is nothing in the
09:34 18 prosecution history. These are the things that the cases
09:34 19 have talked about being important.

09:34 20 If you look at the two cases that were cited in
09:34 21 the briefs primarily -- one was the Honeywell case. In that
09:34 22 case, the Court found that there was a limitation, but in
09:35 23 that case, there were four separate statements that the
09:35 24 Court relied upon, so it was uniform. It was consistent.

09:35 25 In the Astrazeneca case that counsel mentioned,

09:35 1 interestingly what the Court noted was that the very first
09:35 2 sentence that described the invention had those six
09:35 3 chemicals. Again, it was unequivocal. Here is our
09:35 4 invention. Here are the six chemicals. It was in the very
09:35 5 first sentence. So the Court found that that first sentence
09:35 6 that told you what the invention was was unequivocal, and
09:35 7 then the entire structure of the patent -- again, you have
09:35 8 to look at the case. The facts are all specific in these
09:35 9 cases obviously, but in that case, it was also the structure
09:36 10 where they were claiming salts from certain categories.
09:36 11 They didn't claim all the salts in the category. That's
09:36 12 part of the Federal Circuit's analysis, too. They picked
09:36 13 and chose.

09:36 14 So they went through and said we have a couple
09:36 15 different categories of salts. We are going to take five
09:36 16 from this one, not all of them. We are going to take one
09:36 17 from this one, not all of them. Those are our six. That's
09:36 18 our invention. Then later when the applicant tries to come
09:36 19 back and says, no, no, no, we are not limited to those, but
09:36 20 we can get other salts in those categories, the Court says,
09:36 21 no, you can't. There is nothing like that here.

09:36 22 These cases are just completely different where
09:36 23 you have got all these broad statements in the abstract. In
09:36 24 Astrazeneca, the Court also noted the abstract was
09:36 25 consistent. Comparing Astrazeneca to the '475 Patent, the

09:36 1 abstract doesn't mention anything about the degree of
09:36 2 cross-linking. The first sentence in the first paragraph
09:36 3 doesn't mention anything about the degree of cross-linking.
09:36 4 Those are the portions of the patent that that Circuit
09:37 5 focused on in Astrazeneca because right up front the
09:37 6 applicants were telling the world here is our invention.

09:37 7 In this case, the applicants told the world what
09:37 8 their invention was up front. Here is what the abstract
09:37 9 say. Here's the problem we are trying to solve. Here is
09:37 10 the summary of our invention. Never mentioned this 2 to 20
09:37 11 range. Later on in column 9 of the patent, there is a
09:37 12 sentence. They are now trying to say that one sentence in
09:37 13 isolation limits the entire disclosure. We think that's
09:37 14 wrong. We think you got it right in the tentative, Your
09:37 15 Honor.

09:37 16 The other point here besides the legal point is
09:37 17 that in their briefing defendants set this up as an
09:37 18 alternative argument. The Court may recall this is related
09:37 19 to the water solubility or insolubility argument that the
09:37 20 the Court has ruled upon and that the parties are now
09:38 21 contesting.

09:38 22 So in their opening brief at pages 13 and 14, they
09:38 23 said --

09:38 24 THE COURT: The Court has ruled upon -- you were
09:38 25 contesting, and I ruled in favor of the defense on water

09:38 1 insolubility.

09:38 2 MR. KANE: We are not arguing that today. We are
09:38 3 not arguing that in the tentative. You did rule against me
09:38 4 on that point.

09:38 5 THE COURT: Against your client.

09:38 6 MR. KANE: Against our client. But in our opening
09:38 7 brief at pages 13 and 14, again, they said it was an
09:38 8 alternative argument, but if you don't include the water
09:38 9 insolubility of the cross-link HA, then you have to include
09:38 10 the 2 percent because we have to have some way to decide is
09:38 11 the HA free HA or cross-linked HA? They repeated that in
09:38 12 their reply brief at seven.

09:38 13 As you said, Your Honor, you ruled against
09:38 14 Allergan on that point. The question I ask then is if they
09:38 15 said it was in the alternative, why do they want it still?
09:39 16 The reason is very simple. They are trying to manufacture a
09:39 17 noninfringement argument, and it is completely inconsistent
09:39 18 with the specification.

09:39 19 THE COURT: Do I take into account the purposes of
09:39 20 claim construction?

09:39 21 MR. KANE: Well, I think it's instructive that
09:39 22 before they had told you it's an alternative and now --

09:39 23 THE COURT: I should construe claims in the
09:39 24 pristine world unaffected by what result it will have? It's
09:39 25 kind of a little conversation I have had with my clerk over

09:39 1 here.

09:39 2 MR. KANE: I understand. I have dealt with judges
09:39 3 in both camps.

09:39 4 THE COURT: And judges in this court.

09:39 5 MR. KANE: So let's just take a look at this. I
09:39 6 think it's instructive because there isn't this
09:39 7 interrelationship. They set it up as you need -- this
09:39 8 limitation is necessary to distinguish free HA from
09:39 9 cross-linked HA. Now, in that argument, they cited four
09:39 10 prior art references that describe the cross-link HA as
09:40 11 water insoluble.

09:40 12 As noted in the briefing, Allergan didn't ever
09:40 13 contest that cross-linked HA was water insoluble. We just
09:40 14 didn't think that was necessary in the construction. They
09:40 15 have identified four references: The Calais reference,
09:40 16 Exhibit 2; the Sadozai reference; Exhibit 4, the Debacher
09:40 17 reference --

09:40 18 THE COURT: You have got the patent there, right?

09:40 19 MR. KANE: I do, Your Honor.

09:40 20 THE COURT: Are you citing references from the
09:40 21 patent?

09:40 22 MR. KANE: No. I'm citing references used by the
09:40 23 defendants to illustrate that cross-linked HA is water
09:41 24 insoluble.

09:41 25 THE COURT: Understood.

09:41 1 MR. KANE: The final reference they cited is
09:41 2 Lebreton, which is Exhibit 6. So they gave you four
09:41 3 references, Your Honor, where they said here's where --
09:41 4 those skilled in the art say that water soluble --
09:41 5 cross-linked HA is insoluble. They have given you zero
09:41 6 references where anyone makes a distinction between free HA
09:41 7 and cross-linked HA based on the degree of cross-linking.
09:41 8 It's always based on the degree of solubility, which the
09:41 9 Court has ruled on.

09:41 10 Their stated purpose was that we need this
09:42 11 limitation to distinguish between these two. The fact is
09:42 12 you don't. For instance, we can show you the Tezel
09:42 13 reference. This is at page 305 of Tezel that the Court
09:42 14 cites in its tentative order. For instance, it says, "The
09:42 15 total HA concentration consists of insoluble HA and soluble
09:42 16 free HA."

09:42 17 So, again, the distinction between HA species --
09:42 18 there are two species in the total HA -- the total
09:42 19 composition: The insoluble HA, the cross-linked HA; and the
09:42 20 soluble-free HA. But it's not based on the degree of
09:42 21 cross-linking.

09:42 22 Then continuing, at the bottom it talks about "The
09:42 23 fluid component contains unmodified and modified soluble HA
09:43 24 that is generated during the manufacturing process when the
09:43 25 HA fragments are formed as a side product of the chemical

09:43 1 modification." And it continues at the very end of this
09:43 2 section: "It is important to understand how much of the
09:43 3 filler's concentration is gel or cross-linked HA and how
09:43 4 much is soluble fluid HA." So solubility or insolubility is
09:43 5 the distinction between free HA and cross-linked HA, and
09:43 6 it's not based on the degree of cross-linking. They haven't
09:43 7 shown you that. They can't show you that.

09:43 8 In fact, Your Honor, again to put this in
09:43 9 perspective, why are they still arguing this? Their product
09:43 10 has insoluble cross-linked HA particles with a degree of
09:44 11 cross-linking of less than 2 percent. If you were to impose
09:44 12 this limitation, there would be a summary judgment motion
09:44 13 they say they don't infringe.

09:44 14 The problem is this. They started off this whole
09:44 15 discussion with we have got this problem. We have got free
09:44 16 HA. We have got cross-linked HA. It has to fall into one
09:44 17 of those two camps, and we can't tell based on Allergan's
09:44 18 constructions. We could debate that, but there is no need
09:44 19 to. They have now created the opposite problem because they
09:44 20 have got undisputed -- this is based on public documents --
09:44 21 cross-linked HA particles less than 2 percent. So it's not
09:44 22 free HA because it's insoluble. Agreed upon definition.
09:45 23 It's not cross-linked HA. Why not? Because it's less than
09:45 24 2 percent. So now they have created this other undefined HA
09:45 25 category that's no longer free HA. It's no longer

09:45 1 cross-linked HA. It's something else.

09:45 2 So the entire premise of their argument that you
09:45 3 have got to add the 2 percent in order to make this bright
09:45 4 line between free HA and cross-linked HA falls apart. The
09:45 5 bright line is the water solubility. This 2 percent is just
09:45 6 an attempt to manufacture an infringement defense.

09:45 7 Again, with the description in the title, the
09:45 8 abstract, the background of the invention, the summary of
09:45 9 the invention, the claim language, the lack of discussion of
09:45 10 this in the specification, the lack of -- it was mentioned
09:45 11 one time -- the lack of it in the claims, there is just
09:45 12 really no way that someone can come away with this and say
09:46 13 this is really the invention. You have to limit the
09:46 14 invention to 2 to 20.

09:46 15 So we think that it doesn't rise to the level of a
09:46 16 clear disclaimer, which is what it has to have. There is no
09:46 17 manifest words of exclusion here where they say our
09:46 18 invention is limited to 2 to 20, and if you are outside that
09:46 19 range, we don't cover it. Again, that's not what this was
09:46 20 about. The invention was about adding Lidocaine and getting
09:46 21 Lidocaine into these gels. That's what they taught. That's
09:46 22 the novel aspect.

09:46 23 THE COURT: Thank you.

09:46 24 To close, sir, how much time do you need?

09:46 25 MR. CAVANAUGH: Three minutes.

09:46 1 THE COURT: I appreciate the argument of both
09:46 2 counsel. It's very helpful.

09:46 3 MR. CAVANAUGH: Your Honor, we do think this is an
09:46 4 aspect of a novel invention, not standing alone 2 to
09:46 5 20 percent, but what counsel never really squarely addressed
09:46 6 is what's the purpose of that statement in column 9: "The
09:46 7 degree of cross-linking in a HA component of the present
09:47 8 compositions is at least 2 percent and is up to about
09:47 9 20 percent"?

09:47 10 What is that teaching a person of ordinary skill
09:47 11 in the art when they read this? You look at the summary.
09:47 12 They make it clear that cross-linking is an aspect of
09:47 13 achieving a functional useful product. When you read this,
09:47 14 you say, well, how do I achieve that? It's between 2 and
09:47 15 20 percent.

09:47 16 In column 3 that they point to --

09:47 17 THE COURT: Do you think the specification in that
09:47 18 range would be patentable?

09:47 19 MR. CAVANAUGH: I don't know the answer to that
09:47 20 standing alone. It might not be. I don't think that their
09:47 21 Lidocaine addition is patentable because there was Lidocaine
09:47 22 in the prior art. Frankly, from our position, we don't
09:47 23 think any of this is patentable. Whether standing alone it
09:48 24 would be, I don't know how precisely the claims would be
09:48 25 phrased for it to try to be patentable, but it could

09:48 1 certainly be an aspect of a novel invention.

09:48 2 Because they are seeking to --

09:48 3 THE COURT: 2 to 20 might be the range that
09:48 4 provides both stability and the ability to use with a
09:48 5 smaller needle.

09:48 6 MR. CAVANAUGH: It's sufficiently viscous that
09:48 7 it's a useable product. The purpose of this range of
09:48 8 cross-linking is that we end up with something that is
09:48 9 functional, that's usable. They are claiming that
09:48 10 cross-linking is important to this process. In the summary,
09:48 11 they talk about the cross-linking process, and then in
09:48 12 column 3, they say less than 5 percent, about 2 percent.

09:49 13 I keep coming back to that dependent claim that
09:49 14 says about 2 percent, and the two prior ones said less than
09:49 15 5, less than 6, and then they stop at about 2 percent.

09:49 16 THE COURT: Is 1 percent less than 5 percent?

09:49 17 MR. CAVANAUGH: 1 percent is less.

09:49 18 THE COURT: Does that act against your position?

09:49 19 MR. CAVANAUGH: Not when you read column 9. They
09:49 20 describe the broad range, and then they give embodiments
09:49 21 that are less than 5 percent, less than 6 percent. There is
09:49 22 not a single example of 1 percent throughout the
09:49 23 specification. In column 3 and in column 9 and in dependent
09:49 24 claim 7, it's always 2 percent.

09:49 25 THE COURT: If I were to send you a settlement

09:49 1 letter and said my client is willing to pay you something
09:50 2 less than \$100,000, do you ever assume that can include \$10,
09:50 3 or would you assume I am willing to pay --

09:50 4 MR. CAVANAUGH: I wouldn't.

09:50 5 THE COURT: That's an argument in your favor.

09:50 6 MR. CAVANAUGH: It is.

09:50 7 THE COURT: Less than 5 percent -- if I said my
09:50 8 offer is something less than \$100,000, you would probably
09:50 9 assume it's \$99,000?

09:50 10 MR. CAVANAUGH: The point is context matters. My
09:50 11 point is when you look at the specification -- the one
09:50 12 sentence here is our range is 2 to 20. The next sentence
09:50 13 says some embodiments are less than 5 percent. I wouldn't
09:50 14 say, oh, you know what that means. That means I can use a
09:50 15 .0001 percent cross-linking agent, and I am still within the
09:50 16 scope of this invention. You wouldn't. That's why context
09:50 17 matters. In the context here where they are talking about
09:50 18 less than 5 percent, less than 6 percent, it comes after
09:51 19 that sentence which describes the range.

09:51 20 THE COURT: To expand or maybe more focus the
09:51 21 hypothetical, if I said will give you something less than
09:51 22 five bucks for your hamburger, I don't think you would take
09:51 23 a buck.

09:51 24 MR. CAVANAUGH: If I reached into my pocket and I
09:51 25 had a quarter, I wouldn't think that that's the range you

09:51 1 were talking about.

09:51 2 THE COURT: Okay. So how much will you give me
09:51 3 for a hamburger today? Why is the language there?

09:51 4 MR. KANE: Well, because again that is part of the
09:51 5 range that they looked at. There is no doubt about that.

09:52 6 What counsel is missing, though -- let's look at
09:52 7 column 9 because he is leaving out an intermediate sentence.
09:52 8 The first sentence says about 2 to 20. He likes that
09:52 9 sentence. The next sentence says between 4 and 12. So they
09:52 10 put a lower limit there. They said 2 to 20, 4 to 12. You
09:52 11 have seen patents, Your Honor. That's very common for
09:52 12 patent owners that draft these things, 2 to 20, 4 to 12,
09:52 13 preferably 6. That's very standard.

09:52 14 Here it says 2 to 20. The next line says 4 to 12.
09:52 15 The next says less than 5. So where is the lower limit?
09:52 16 They knew how to put a lower limit in. They did it right
09:52 17 before. They said 4 to 12. If they wanted to say 2 to 5,
09:52 18 they would have had said 2 to 5. They didn't. Context is
09:52 19 important. That's the point I would make, Your Honor. When
09:53 20 they wanted the claim ranges or to talk about ranges, they
09:53 21 did, and they didn't do it on less than 5.

09:53 22 THE COURT: Okay.

09:53 23 MR. CAVANAUGH: Your Honor, as to the sentence
09:53 24 counsel just quoted, he omitted the first three words that
09:53 25 starts that sentence, "In some embodiments, the degree of

09:53 1 cross-linking is about 4 to 12," which follows the opening
09:53 2 sentence, which is "the degree of cross-linking in HA
09:53 3 component of the present compositions." Not some
09:53 4 embodiments, some limitations. Start with the range. Then
09:53 5 provide some embodiments.

09:54 6 Your Honor asked both of us the question where is
09:54 7 the inconsistency? Did counsel come up and say, well, no,
09:54 8 there is an example there where they are using 1 percent or
09:54 9 5 percent or 22 percent? None. None. That's why we say
09:54 10 the specification is consistent, Your Honor.

09:54 11 THE COURT: Okay. Surrebuttal.

09:54 12 MR. KANE: Your Honor, again, it's not
09:54 13 inconsistent as we said before. Again, if they wanted to
09:54 14 say 2 to 5, they could have said 2 to 5. They didn't say
09:54 15 it.

09:54 16 THE COURT: Okay. Counsel is the matter
09:54 17 submitted?

09:54 18 MR. CAVANAUGH: Yes, Your Honor.

09:54 19 MR. KANE: Yes, Your Honor.

09:54 20 THE COURT: I will take it under submission. You
09:54 21 can expect an order probably later today if I check out a
09:54 22 few things I need to check out.

09:54 23 Where are we in the case?

09:54 24 MR. CAVANAUGH: We are in the process of document
09:55 25 production.

09:55 1 THE COURT: Where are you in settlement
09:55 2 discussions?

09:55 3 MR. CAVANAUGH: I know there have been some
09:55 4 discussions between in-house attorneys, and I got an e-mail
09:55 5 today that I think there will be some further discussions.
09:55 6 That's really where we are.

09:55 7 THE COURT: Okay. On the way out, Counsel, just
09:55 8 raise the issue of settlement and maybe talk about what the
09:55 9 future would look like. I recently had a case come up for
09:55 10 trial and was just about ready to call a jury, and they
09:55 11 confessed they had not appeared before a third party in any
09:55 12 of their settlement discussions. You are required to appear
09:55 13 before a third party, and there are a few options available
09:55 14 to you. I don't know if you have thought about that, a
09:55 15 private company, a magistrate judge, or our panel of
09:55 16 attorneys.

09:55 17 Have you decided amongst yourselves which of those
09:56 18 would be preferred?

09:56 19 MS. FLANAGAN: I believe we selected private
09:56 20 mediation in our scheduling order.

09:56 21 THE COURT: That's what I recall, too. So talk
09:56 22 about how you might select someone as a private mediator.
09:56 23 We have got some pretty good patent guys.

09:56 24 Anything else?

09:56 25 MR. CAVANAUGH: No, Your Honor.

THE COURT: Thanks for the argument. It was very helpful.

(Whereupon, the proceedings were concluded.)

* * *

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CERTIFICATE

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Date: August 14, 2014

/s/ Sharon A. Seffens 8/14/14

SHARON A. SEFFENS, U.S. COURT REPORTER

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